Correspondence

The Editorial Board will be pleased to receive and consider for publication correspondence containing information of interest to physicians or commenting on issues of the day. Letters ordinarily should not exceed 600 words, and must be typewritten, double-spaced and submitted in duplicate (the original typescript and one copy). Authors will be given an opportunity to review any substantial editing or abridgment before publication.

More on 'The 11th Myth' About FDA

TO THE EDITOR: I am writing in support of Dr. Ungerleider's letter to the editor, "The 11th Myth," published in the February issue of THE WESTERN JOURNAL OF MEDICINE, and also in reaction to Food and Drug Administration (FDA) Commissioner Donald Kennedy's letter of rebuttal in the March issue.

I think the concern that Dr. Ungerleider reflects is shared by hundreds if not thousands of physicians across the United States relative specifically to the FDA and, more broadly, to other regulatory governmental agencies. Verification of this hypothesis comes in part from the rapid response we have received from hundreds of the top doctors in the United States in response to our Arnold Mandell Defense Fund. Our nation's top physicians in alcohol, drug and psychiatric care share a common concern with the government's apparent rejection of the concept of clinical judgment and its excessive reliance on the *Physicians' Desk Reference* (PDR) to establish appropriate medical indications and dosage. In this regard, I am also concerned by communications I have received, as a member of the American Medical Association's Drug Abuse Advisory Committee, from the FDA via Dr. Kennedy's office, which indicate they are aware of no alternative regulatory mechanisms to deal with issues such as amphetamine control except through reduction of medical indications. In fact, abundant testimony and documentation have been presented that clearly demonstrate that the vast majority of practicing physicians prescribe responsibly and will respond best to education, consultation and peer communication. Most doctors had decreased or eliminated their prescribing of amphetamines well before the FDA hearings, held to restrict the medical indications for amphetamines in December 1977.

In addition, abundant evidence has been presented that the vast majority of drug diversion via the physician route is coming from a few "script" doctors. The diversion investigation units (DIU) created by the Drug Enforcement Administration (DEA) have been the most appropriate way to deal with these script doctors. For example, I have consulted on two cases recently in which nine script doctors in the city of San Francisco prescribed over 55 percent of the city's Schedule II drugs and two other doctors, in the Santa Clara and San Jose areas in California, prescribed 3.5 percent of the *nation's* supply of Ritalin®. The FDA action on reducing indications for amphetamines or other stimulant drugs will have no impact on these script doctors and only concerted action by both the medical community and the DEA can control such diversion. However, the vast majority of responsible physicians should not be penalized because of the illegal and criminal actions of a few.

I also would like to emphasize some information in rebuttal to Commissioner Kennedy's letter, and as underpinning for Dr. Ungerleider's concern. For example, the Commissioner stated that Canada has eliminated obesity as an indication for amphetamine, apparently to justify support for his belief that equivalent regulatory measures will reduce amphetamine abuse in the United States. In fact, on a recent visit of mine to the Royal Canadian Mounted Police in Toronto, Ontario, they indicated that there has been no diminution in amphetamine abuse since obesity was eliminated as an indication. They further indicated to me that diversion from legitimate practicing physicians was *never* a major source of abuse of these drugs on the street.

I do hope that Dr. Kennedy is sincere in his statement that the "FDA's hopes for communication with health professionals are genuine," for if he is sincere in his desire he will begin to listen to ideas for alternative regulatory mechanisms, vis-a-vis controlled substances and the related concerns of practicing physicians and he will begin to act

accordingly. This would be a major step toward helping reduce some of those very valid concerns expressed in Dr. Ungerleider's letter and showing physicians in general that the "Ten Medical Myths About FDA"[1] really are only myths.

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REFERENCE

1. Kennedy D: Ten medical myths about FDA. West J Med 127: 529-534, Dec 1977

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TO THE EDITOR: It is difficult not to be saddened by Federal Drug Administration (FDA) Commissioner Kennedy's comments (Correspondence, March issue) regarding Dr. Arnold Mandell, especially at a time when his authoritative voice is so badly needed. In his reply to Dr. Ungerleider's letter "FDA—The 11th Myth" (Correspondence, February issue), Dr. Kennedy states: "As to the bizarre events surrounding Dr. Arnold Mandell's brief involvement with the National Football League, they are obviously beyond the point here—which is perhaps fortunate, since they are also beyond my comprehension." Kennedy quotes his earlier statement (Ten medical myths about FDA, West J Med 127:529-534, Dec. 1977) that " 'the important consideration is whether departure from approved indications is documented by a *legitimate scientific rationale* for such use' (italics added)." He adds "That determination is in the hands of 50 legal jurisdictions, and out of FDA's."

It may be technically correct that FDA has no control over the interpretations placed upon its regulations by the several state boards and agencies. But what the commissioner says about these regulations is very important. The phrase "legitimate scientific rationale" is one that requires some explication. In the case of Dr. Mandell, for example, what would the commissioner accept as "scientific"? Is it scientific to extrapolate from the accumulated experience of physicians who work in the field of drug dependence? Such physicians recognize that one may at times prescribe the very drugs upon which the patient has become dependent, while simultaneously engaging him in a contract to work toward elimination of the dependency. Is this scientific? Is it "legitimately" (if such a distinction is necessary) scientific? One senses, from what Dr. Kennedy does not say, that he views Dr. Mandell's prescribing practices in regard to the San Diego Chargers as failing to meet one (and thus both) of these criteria. If so, it would be helpful for him to say so, making it possible to debate the issues more openly. His comment that the events surrounding the Mandell case are beyond his comprehension is unfortunate, since these events raise issues of vital concern to all physicians. Primary among them is the validity of clinical judgment, *endorsed by fellow professionals who specialize in the same field,* as a guide to therapy. If such judgment does not constitute a "legitimate scientific rationale" then a crisis is in store for American medicine.

The Mandell case also speaks to another issue, not commented upon by Dr. Kennedy: the need to do something about amphetamine self-medication in professional sports. If the FDA is truly concerned about the adverse consequences of improper drug use, it will gird up its loins and take on this long-standing, shamefully neglected, problem. Even if it has no jurisdiction in this area, an official FDA statement confirming the existence of the problem and urging the football establishment to "clean up its act" would be a courageous and effective beginning. Admittedly there are serious political risks in tampering with an industry whose gate receipts and TV sponsorships might be badly hurt by such an intrusion, but Commissioner Kennedy could at least be assured that in this battle he would undoubtedly have the overwhelming support of the medical profession.

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Gerontology and Geriatrics

TO THE EDITOR: In reference to your editorial "Thoughts About Geriatrics" and Alex Comfort's article "Geriatrics—The Missing Discipline?", both contained in the March 1978 issue—A resounding and exuberant bravo.

While the field of gerontology continues to mature at a very rapid pace and impetus has increased in recent times about the issues of human aging and the specialized medical needs of aging and aged persons; data, action and follow-up remain for the most part negligible. There are few gerontologists, researchers and even fewer medical schools and medical practitioners engaged in the training and delivery of medical care to the nation's growing aged population. Historically, the few who have engaged in such research, training and medicine confine their efforts to pharmacological research and inter-